K052566

1 of 2

JAN 6 2006

ABBOTT SPINE, INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Abbott Spine Inc. (formerly Spinal Concepts, Inc.)
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	Noah Bartsch Specialist, Regulatory Affairs Telephone: 512.533.1840 Fax: 512.918.2784
DATE:	September 16, 2005
TRADE NAME:	Nex-Link Spinal Fixation System Polyaxial Screws, Open Hooks
COMMON NAME:	Posterior Spinal Implant
CLASSIFICATION NAME:	KWQ: Spinal Intervertebral Body Fixation Orthosis MNI: Pedicle Screw Spinal System
CLASSIFICATION REFERENCE:	21 CFR § 888.3050, 888.3070
PREDICATE DEVICE:	Spinal Concepts, Inc. (now Abbott Spine, Inc.) Nex-Link Spinal Fixation System, K031985, cleared September 11, 2003.

DEVICE DESCRIPTION:
The Nex-Link Spinal Fixation System is intended for fixation to, and stabilization of, the cervicothoracic spine (C1-T3). The system consists of a series of longitudinal members, anchors, transverse connectors, and instruments for inserting and securing the implants.

The subject devices are the result of design modifications made to previously existing Abbott Spine implants intended for use in the posterior spine. The subject devices share the same intended use and fundamental scientific technology as the predicates.

INDICATIONS:
When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the NexLink Spinal Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The use of multiaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. The multiaxial screws are not intended to be placed in the cervical spine.

COMPARISON TO PREDICATE DEVICE:	The subject devices are the result of design modifications to the predicate devices; they have the same intended use and are substantially equivalent to the predicate devices.
PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):	NON-CLINICAL PERFORMANCE AND CONCLUSIONS: Laboratory and bench testing results demonstrate that the proposed devices are substantially equivalent to the predicate devices. CLINICAL PERFORMANCE AND CONCLUSIONS: Clinical data and conclusions were not needed for this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Mr. Noah Bartsch
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K052566
Trade Name: Nex-Link™ Spinal Fixation System – Addition of Open Polyaxial Screws and Hooks
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNI, KWP
Dated: December 12, 2005
Received: December 13, 2005

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number : K052566

Device Name: Abbott Spine Incorporated's Nex-Link Spinal Fixation System – Addition of Open Polyaxial Screws and Hooks

Indications For Use:

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the Nex-Link Spinal Fixation System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The use of multiaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. The multiaxial screws are not intended to be placed in the cervical spine.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052566